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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,937	05/24/2002	Dominique Roecklin	111664	3978

7590 12/21/2004
Oliff & Berridge
PO Box 19928
Alexandria, VA 22320

EXAMINER

MARTINELL, JAMES

ART UNIT PAPER NUMBER

1631

DATE MAILED: 12/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/030,937

Applicant(s)

ROECKLIN ET AL.

Examiner

James Martinell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-23, 26-30, 33, 60 and 61 is/are pending in the application.
- 4a) Of the above claim(s) 33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-23, 26-30, 60 and 61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 January 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: Appendices A&B

Claim 33 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on October 14, 2004. Applicants' arguments in connection with the requirement for restriction mailed September 15, 2004 are persuasive in part. The elected Group I has been rejoined with claims 26-30, 60, and 61 of Group II in view of applicants' arguments. Group III (claim 33) drawn to nucleic acids does not share a common special technical feature with the polypeptides of Group I as is asserted by applicants. Nucleic acids and polypeptides have different structures and are materially different substances. Thus, claims 19-23 and 26-30, 60, and 61 are examined here on the merits and claim 33 is withdrawn from consideration.

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. Embedded hyperlink and/or other form of browser-executable code appear in at least the following location:

- (a) page 4, line 30.

Copies of references submitted May 24, 2002 have not been considered because not all of the requirements for submitting an Information Disclosure Statement have been met (see MPEP 609, especially part III).

The drawings are objected to because Figure 1-3 do not comply with the Sequence Rules (37 CFR §§ 1.821-1.825). Figures 1-3 disclose amino acid and nucleic acid sequences without identifying SEQ ID NOs. See MPEP 2422 and 37 CFR § 1.821(d). Correction may be made either to the drawing *per se* or by addition of the appropriate SEQ ID NOs into the discussion of the Figures in the specification. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing

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figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19-23 and 26-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are vague, indefinite, and incomplete.

- (a) The recitation of "peptide sequence corresponds to SEQ ID No: 9" (claims 19, 22, and 23) is vague and indefinite because it is not clear whether the claimed sequences actually have the sequence of SEQ ID NO: 9. The precise meaning of "corresponds to" is not clear. Thus, the metes and bounds of the claims are not clear.
- (b) The recitation of "peptide sequence in the native state corresponds to SEQ ID No: 1 to SEQ ID No: 8 and SEQ ID No. 10 to SEQ ID No: 29" (claim 27) is vague and indefinite because it is not clear whether the claimed sequences actually have the sequences of the SEQ ID NOs mentioned in the claim. The precise meaning of "corresponds to" is not clear. Thus, the metes and bounds of the claims are not clear.

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- (c) The recitation of "belonging to the same family of proteins chosen from Perlecan, the precursor of the retinol-binding plasma protein, precursor of the ganglioside GM2 activator, calgranulin B and saposin B" (claim 27) is vague and indefinite because there are no art-accepted definitions for any of these terms, nor are they defined with specificity in the instant application. Thus, the metes and bounds of the claim are not clear.
- (d) The recitation of "ligand specific for said polypeptide" (claim 29) is vague, indefinite, and incomplete because specificity of binding depends upon the presence of molecules in the reaction mixture that compete for binding to the target polypeptide. Thus, the claims are vague, indefinite, and incomplete in the absence of mention of the potential competing molecules.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19-23, 26-30, 60, and 61 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polypeptides of defined sequence and methods using polypeptides of defined sequence, does not reasonably provide enablement for all of the polypeptides embraced by the claims or methods requiring their use in the claimed method. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The CAFC in *In re Wands* (*In re Wands*, 8 USPQ2d 1400, Fed Cir. 1988) listed various factors to be considered in determining enablement. They include:

- (1) The quantity of experimentation necessary

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- (2) The amount of direction or guidance presented
- (3) The presence or absence of working examples
- (4) The nature of the invention
- (5) The state of the prior art
- (6) The relative skill of those in the art
- (7) The predictability of the art
- (8) The breadth of the claims

Each of these factors is discussed below.

The quantity of experimentation necessary

A great amount of experimentation would be necessary considering the large number of polypeptides recited in the claims. To arrive at an assay that would work and yield meaningful results would involve the testing of a large number of combinations of materials and parameters. In addition, the instant application does not disclose whether any sequences other than those actually disclosed occur naturally. To discover other naturally occurring sequences that are embraced by the claims would involve undue experimentation, since it is not known or predictable which species may harbor such sequences.

The amount of direction or guidance presented

The instant application does not provide guidance as to which of the large number of polypeptides embraced by the claim would work as claimed (*e.g.*, see the recitation of 'at least 70% identity').

The presence or absence of working examples

There is no working example beyond the specifically disclosed sequences.

The nature of the invention

The invention is in the field of biochemistry and molecular biology.

The state of the prior art

The prior art of record does not indicate whether other sequences may exist. The prior art of record does not indicate which parts of the GM2 Activator Protein may be modified without destroying its activity.

The relative skill of those in the art

The relative skill of those in the art is high. The person with skill in the art most likely in possession of a Ph.D. degree and at least some post-doctoral research experience.

The predictability of the art

In view of the lack of prior art for the claimed method, the predictability is low.

The breadth of the claims

The claims are very broad in that they encompass large (and indefinite) "families" of proteins and also embrace proteins that exhibit at least 70% identity with any one of 28 different proteins. For example, the number of polypeptide sequences that contain insertion mutations only and that are at least 70% identical to SEQ ID NO: 1 (4393 amino acids in length) alone is no less than 6.90×10^{2876} .

After consideration of all of these factors, the claims are deemed not enabled for their full scope.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 19, 22, and 23 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Xie et al (Biochem. Biophys. Res. Comm. 177: 1217 (1991)). Xie et al discloses a polypeptide with all of the claimed features (see the alignment in Appendix A).

Claims 19, 22, and 23 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Nagarajan et al (Biochem. J. 282: 807 (1992)). Nagarajan et al et al discloses a polypeptide with all of the claimed features (see the alignment in Appendix B).

Claims 26, 28-30, 60, and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over either one of Xie et al (Biochem. Biophys. Res. Comm. 177: 1217 (1991)) or Nagarajan et al (Biochem. J. 282: 807 (1992)) in view of Li et al (J. Biol. Chem. 270: 24246 (1995)). Each of the primary references discloses polypeptides that encode mutants (in relation to SEQ ID NO: 8 of the instant application) of GM2 Activator Protein (see Appendices A and B). Li et al teaches the detection of GM2 Activator Protein using monoclonal antibody assays (*e.g.*, see the Material section on page 24247). It would have been obvious for one of ordinary skill in the art at the time the invention was made to assay for the GM2 Activator Protein polypeptides of either one of the primary references using the methods of Li et al in order to detect GM2 Activator Protein.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James Martinell whose telephone number is (571) 272-0719. The fax phone number for Examiner Martinell's desktop workstation is (571) 273-0719. Only documents such as those intended for use in a personal or telephone interview should be faxed to the examiner's desktop workstation. Any Official Communication to the USPTO should be faxed to (571) 273-8300.

The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be e-mailed to james.martinell@uspto.gov. Since e-mail communications may not be secure, it is suggested that information in such requests be limited to name, phone number, and the best time to return the call.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-0722.

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OFFICIAL FAX NUMBER

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300. Any Official Communication to the USPTO should be faxed to this number.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.


James Martinell, Ph.D.
Primary Examiner
Art Unit 1631

12/18/04

SOURCE Homo sapiens (human)
 ORGANISM Homo sapiens
 Eukaryota; Metazoa; Chordata; Craniata; Vertebrata; Euteleostomi;
 Mammalia; Eutheria; Primates; Catarrhini; Hominoidea; Homo.
 REFERENCE 1 (bases 1 to 2436)
 AUTHORS Klima, H., Tanaka, A., Schnabel, D., Nakano, T., Schroder, M., Suzuki, K.
 TITLE Characterization of full-length cDNAs and the gene coding for the
 human GM2 activator protein
 JOURNAL FEBS Lett. 289 (2), 260-264 (1991)
 MEDLINE 92008637
 PUBMED 1915857
 REFERENCE 2 (bases 1 to 2436)
 AUTHORS Klima, H., Klein, A., van Bellen, G., Schwarzmann, G., Suzuki, K. and
 Sandhoff, K.
 TITLE Over-expression of a functionally active human GM2-activator
 protein in Escherichia coli
 JOURNAL Biochem. J. 292 (Pt 2), 571-576 (1993)
 MEDLINE 93277527
 PUBMED 8503891
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 Best Local Similarity: 98.964 Mismatches: 2
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 DB: 9 Gaps: 0

US-10-030-937-9 (1-193) x HSGM2AFT (1-2436)

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 119 GGGCAAGCCACCTTAAAAAGCATCCAGCTGATGCTTTCCCGGATACCTGAT 178
 41 GAGGGLYAAAPPROALVALLEAERSELEUThLEUENLAPROASPProILEVALVAL 60
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 QY 101 AAPTYYILEGYSERCYSTRPHEGWIHISPECISAPVALLEUASPMELEULEIPRO 120
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 QY 121 THRGLYUROCYSAPROGLUPTROLEUATGTHYRGLYLEUPTROCYSHISYSPROPE 140
 DB 419 ACTGGGAGCCCTGACCCAGAGCCCTGCGTACCTATGAGGCTTCTCCACTTCCCTTC 478
 QY 141 LYSGLUQYLYTHYRSELEUPROLYSERGLUPHEALVALPROASPENGLULEUPRO 160
 DB 479 AAGAGAGACCTACCTACCTGACCCAGAGCCATTCCTGCTGACCTGAGGCTGCC 538
 QY 161 SEITRPLEUThRGLYASNTYRGLILEGUSERVALLEUSERSERSEGLYLYSARG 180
 DB 539 AGTTGCTACCAAGCGGAACTACCGCATAGAGGCTGCTGAGCAGCAGTGGAGAGCCT 598
 QY 181 LEUGLYCYSLLEYSLLEALASERLEUULEYSLYILE 193
 DB 599 CTGGGCTGCATCAGATGCTGCTGCTGCTGCTGCTGCTGCTGCTGCTGCTGCTGCTG 637

RESULT 4

HOMO2
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 DEFINITION M76477.1 GI:183356
 ACCESSION M76477.1 GI:183356
 VERSION M76477.1 GI:183356
 KEYWORDS G-M2 activator protein.
 SOURCE Homo sapiens (human)
 ORGANISM Homo sapiens
 Eukaryota; Metazoa; Chordata; Craniata; Vertebrata; Euteleostomi;
 Mammalia; Eutheria; Primates; Catarrhini; Hominoidea; Homo.
 REFERENCE 1 (bases 1 to 953)
 AUTHORS Xie, B., McInnes, B., Neote, K., Lambonvah, A.M. and Mahuran, D.
 TITLE Isolation and expression of a full-length cDNA encoding the human
 GM2 activator protein
 JOURNAL Biochem. Biophys. Res. Commun. 177 (3), 1217-1223 (1991)
 MEDLINE 91282768
 PUBMED 2059210
 COMMENT source text: Homo sapiens mRNA.
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ORIGIN

ALIGNMENT SCORES:
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 Percent Similarity: 98.458 Conservative: 0
 Best Local Similarity: 98.458 Mismatches: 3

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23	1 MEUHSERLEUWETGHNALAPROLEU11EALAEUGLYLEU1EUA1ATHRPRO	20
24	22 ATGCAGTCTCCCTATACAGAGCTCCCTCTCTATGCGCCCTGGCTCTCTCGGGCCCT	81
25	21 AlaGlnAlaHisLeuValylProSerGlnLeuSerSerPheSerTyrPheGlyPhe	40
26	82 GCCCAAGCCCACTGCAAAAAGACCTCCAGCTCATGACTCTTTCCTGGATCTGAT	141
27	41 GluGlyLeuAspProAlaValIleAspSerLeuThrLeuGluProAspProIleVal	60
28	142 GAAAGGAAGAACCTCGCGGTATACAGAGCTGACTGAGAGCTGACCCCATATCTT	201
29	61 ProGlyAsnValThrLeuSerValGlySerThrSerValProLeuSerSerProLeu	80
30	202 CCTGGAAAATGATACCTCAGTGTATCGGCAACAACATGCCCCCTGAGTTCTCTCTG	261
31	81 LysValAspLeuValLeuGlyLysGluValIleGlyLeuTyrIleValIleProGlyThr	100
32	262 AAGTGTGATTGATTGGTTCGAAAGAGAGCGTGGCTCGCTGTGATCAATATCCATGACA	321
33	101 AspTyrIleGlySerGlyThrPheGlyIlePheGlyValLeuAspMetLeuIlePro	120
34	322 GACTCATTTGGCACTGACTTACCTTGAACCTTGTGATGCTTACATCATGTTAATTCCT	381
35	121 ThrGlyGluProGlyPheGluProLeuAlaGlyThrTyrGlyLeuProGlyAsnIleGlyPhe	140
36	382 ACTGGGAGAGCCCTCCAGAGCCCTCGCTCATATAGGCTCTCTTGGCCACTGTCCTTC	441
37	141 LysGlyGlyThrTyrSerLeuProLysSerGluPheAlaValProAspLeuGluPro	160
38	442 AAGAAGAGAACCTACTACTGCGCAAGACCAATTCCTGTGCTTACTGAGACTGCC	501
39	161 SerTyrLeuThrTrpGlyAsnTyrAlaGlyIleGlySerValLeuSerSerSerGlyLysArg	180
40	502 AGTTGGCTCAACCAACCGCAATCCGCAATGAGAGGCTCTTGAAGCAGCAGTGGAGAGCT	561
41	181 LeuGlyGlyIleLysIleIleAlaSerLeuLysGlyIle	193
42	562 CTGGGCTGCATCAAGATCTCGCTCTCTTAAAGGACATA	600

[illegible]